

Inventors: Osborne and Ramesh
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implanting into an individual cells coexpressing proinsulin containing a proinsulin cleavage site, a glucose-regulated protease capable of cleaving said proinsulin cleavage site to produce insulin, and a hexosamine biosynthetic pathway enzyme.

REMARKS

Claims 1-40 are pending in the above-identified application. Claims 17-39 are currently under examination. By the present communication claims 17 and 28 have been amended. Support for the amendments can be found in the specification, for example, on page 13, line 13, through page 14, line 5. Marked up versions of the amended claims are provided in Appendix A, attached hereto.

Claims 17-39 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification while being enabling for treatment of diabetes, does not reasonably provide enablement for preventing diabetes. In this regard, the Office Action alleges that delivering insulin to a diabetic individual is not recognized as preventing or curing diabetes but as alleviating the symptoms of diabetes that are associated with insulin supplementation. The Office action further alleges that one skilled in the art would not be able to predict that the claimed methods would be able to prevent the onset or progression of diabetes in an individual.

Applicants respectfully traverse this rejection and submit that the specification, on page 13, lines 13-15, defines

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"preventing" to mean forestalling of a clinical symptom indicative of diabetes. According to the teachings in the specification those skilled in the art would have been able to use the claimed methods to prevent diabetes, or forestall a clinical symptom indicative of diabetes, at the time the application was filed. Nevertheless, in order to further prosecution of this application, claims 17 and 28 have been amended to recite a method of treating diabetes or forestalling a clinical symptom indicative of diabetes. Therefore, the amendments merely modify the claims to recite the definition of the term "preventing" as it is taught in the specification.

Applicants respectfully submit that one skilled in the art would have recognized the onset or progression of diabetes according to clinical symptoms as taught in the specification, for example, on page 9, line 12, through page 13, line 9, where characterization of diabetes by a variety of clinical symptoms such as glucose intolerance or hyperglycemia is taught. A variety of other clinical symptoms can also be used to determine onset or progression of diabetes including, for example, muscle wasting, ketoacidosis, glycosuria, polyuria, polydipsia, diabetic microangiopathy or small vessel disease, atherosclerotic vascular disease or large vessel disease, neuropathy or cataracts as taught on page 10, through 11 and listed in Table 1. As taught in the specification, the claimed methods can be used in individuals displaying these or any clinical symptoms to prevent the progression of a symptom of diabetes from the guidance in the specification including, for example, on page 23, lines 3-14, which teaches that cells of the invention secreting insulin in

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response to elevated glucose levels can be used to treat diabetes. The specification also teaches that the methods can be used as a prophylactic treatment, for example, on page 13, lines 15-19, which states that "forestalling includes, for example, the maintenance of normal levels of blood glucose in an individual at risk of developing diabetes prior to the development of overt symptoms of the disease or prior to diagnosis of the disease." Therefore, those skilled in the art would have recognized that the claimed methods can also be used to prevent the onset of a symptom of diabetes in an individual at risk for contracting the disease.

Furthermore, the specification teaches routine methods for making and using cells to prevent the progression of a symptom of diabetes or prevent the onset of a symptom of diabetes. For example, the specification teaches routine methods for making cells expressing insulin on page 80, lines 14-24, and page 81, line 24, through page 82, line 3, where production of smooth muscle cells secreting insulin is taught. The specification teaches on page 83, line 1, through page 84, line 25 that use of these cells in the claimed methods prevented high blood glucose and the need for exogenously added insulin in diabetic rats. Thus, undue experimentation would not have been required to make and use the cells of the claimed method in a way that could prevent the progression of a symptom of diabetes or prevent the onset of a symptom of diabetes in an individual at risk for contracting the disease.

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Applicants respectfully submit that the amendments render the rejection moot. Accordingly, Applicants respectfully request that rejection of claims 17-39, under 35 U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call Cathryn Campbell or the undersigned agent.

Respectfully submitted,

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APPENDIX A

17. (Amended) A method of treating [or preventing] diabetes or forestalling a clinical symptom indicative of diabetes comprising implanting into an individual cells coexpressing proinsulin containing a proinsulin cleavage site and a glucose-regulated protease capable of cleaving said proinsulin cleavage site to produce insulin.

28. (Amended) A method of treating [or preventing] diabetes or forestalling a clinical symptom indicative of diabetes comprising implanting into an individual cells coexpressing proinsulin containing a proinsulin cleavage site, a glucose-regulated protease capable of cleaving said proinsulin cleavage site to produce insulin, and a hexosamine biosynthetic pathway enzyme.